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Office of The Attorney General
State of Connecticut

July 27, 2007

Andrew C. von Eschenbach, M.D.
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Re: Connecticut Citizens Petition - 2004P - 0043

Dear Dr. von Eschenbach:

I am writing to urge you to issue a decision on a Citizen Petition ("Petition") I filed with the Food and Drug Administration ("FDA" or "agency") more than three years ago. In that Petition, I requested that the FDA require Purdue Pharma L P ("Purdue") to revise the labeling of OxyContin® Tablets ("OxyContin") to expressly warn prescribers of the increased occurrence of side effects or potentially serious adverse reactions resulting from prescribing OxyContin off-label at dosing intervals less than the manufacturer's recommended every 12 hours. The recent conviction of Purdue and several of its present and former executives on charges that they misled prescribers and the public about OxyContin's risk of addiction underscores the need for the labeling changes requested in my Petition.

The Petition was filed on January 23, 2004, initially in redacted form due to documents supporting the Petition that had been designated "confidential" by Purdue. On July 21, 2004, the FDA sent my Office an interim response indicating that the agency was unable at the time to reach a decision "because the petition raises significant and complex issues requiring extensive review and analysis…"

On March 16, 2005, this Office supplemented the original redacted Petition with the entire unredacted version of the Petition to ensure that the full weight of the evidence supporting the Petition would be available for consideration by the FDA prior to its rendering a final decision on the critical public health interests raised therein.

On September 28, 2006, having received no further response, I wrote to the FDA requesting the status of the FDA's review of the Petition and asking when we might expect your ruling on the important issues raised in the Petition, To date, I have received no response to the letter or a substantive response to the Petition.

As I am sure you are aware, there have been several recent developments on the legal front related to OxyContin and Purdue that underscore the urgency of the issues raised in the Petition. First, on May 8, 2007, my Office, in collaboration with 25 other states and the District of Columbia, entered into a $19.5 million dollar settlement with Purdue. That settlement was prompted by Purdue's failure adequately to disclose abuse and diversion risks associated with OxyContin, and the company's failure to take sufficient action or provide adequate warnings to prevent the potential harm that occurs from the off-label dosing regimen of less then every 12 hours

Second, on May 10, 2007, Purdue and three of its senior executives pleaded guilty in federal court to charges of misbranding OxyContin. Among the charges in the criminal Information are that Purdue supervisors and employees misled prescribers by marketing OxyContin and claiming that the drug resulted in less euphoria and less potential for abuse.[1] The conduct at the heart of both the Attorneys General settlement and the U.S. Attorney's investigation includes some of the very same information detailed in the Petition, which underlies the actions I have requested the agency to take to remedy these public and patient safety concerns. Just last week, the federal court ordered Purdue and its three executives to pay fines totaling $634.5 million for misleading the public about OxyContin's risk of addiction.

It has now been three and a half years since the FDA received my initial Petition and close to two and a half years since the agency received the additional information supplementing the Petition. To date, other then the "interim response" that more time was needed to evaluate the issues raised, we have received no other information, much less a final decision on our requests.

Given the serious risks to the public safety and health, I ask that the FDA issue its formal decision on the Petition and order the label warnings as quickly as possible. In the meantime, I ask that you provide information regarding (1) the status of the FDA's review and when we might expect a ruling; (2) whether any preliminary decisions or conclusions have been reached regarding the Petition; and (3) whether any additional information could be provided by my Office to the FDA to assist it in coming to a resolution on this issue.

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1 Purdue has agreed that the facts alleged in the federal government's criminal Information are true. *U.S. v The Purdue Frederick Co , Inc et al ,* No. 1:07CR00029, 2007 U.S. Dist LEXIS 53042, at *3 (WD VA July 23, 2007)

In light of the relevance of the Petition to the Senate Committee on the Judiciary's upcoming hearing on July 31, 2007 entitled *"Ensuring that Death and Serious Injury are More than a Business Cost OxyContin and Defective Products "*, I am sending copies of this letter and the Petition to the Chairs of the committee.

I look forward to your prompt response.

Very truly yours,

RICHARD BLUMENTHAL

Cc: Sen., Patrick J. Leahy (w/enclosure) Sen. Arlen Specter (w/enclosure)
U.S. Senate Committee on the Judiciary

Howard Udell, Esq (w/o enclosure) Purdue Pharma, L.P.